

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)						February 2002				
BUDGET ACTIVITY 4 - Demonstration/validation			PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev							
COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost		14970	19872	10398	10245	11309	10687	11076	Continuing	Continuing
808	DOD DRUG & VACC AD	4484	4038	5250	5285	5286	4317	4415	Continuing	Continuing
811	MIL HIV VAC&DRUG DEV	5529	6286	0	0	0	0	0	0	17752
836	COMBAT MEDICAL MATL AD	4134	4164	4260	4210	4258	4198	4394	Continuing	Continuing
837	SOLDIER SYS PROT-AD	823	884	888	750	1765	2172	2267	Continuing	Continuing
MD4	FUTURE MEDICAL SHELTER	0	3500	0	0	0	0	0	0	3500
MD5	IMED TOOLS RURAL MOBILE COMMS	0	1000	0	0	0	0	0	0	1000
<p><b><u>A. Mission Description and Budget Item Justification:</u></b>This program element (PE) funds the advanced development of medical materiel necessary to field an effective capability for counteracting infectious diseases, treating, diagnosing and evacuating combat casualties, and developing operational medical drugs and materiels. The PE funds advanced development of systems for medical protection against naturally occurring diseases and human immunodeficiency virus (HIV). These initiatives directly enhance military forces deployability and survivability through preventative protection against expected threats in areas of potential conflict around the globe. This includes development and initial human testing of vaccines, prophylactics, and therapeutic drugs. Additionally, the PE supports advanced development of field medical equipment and drugs essential for combat casualty care on all battlefields and military operations other than war. Systems include resuscitators, blood substitutes, advanced sensors and diagnostic algorithms, field x-ray, field production of medical grade oxygen, intensive care delivery platforms and litters, and hemostatic dressing. These products have the potential to significantly enhance force sustainment (both physiologically and psychologically) by providing a more responsive, versatile, and empowered forward health care. The PE also funds advanced development of systems that provide enhancement of or protection against physiological and psychological factors affecting cognitive and physical performance imposed by military systems, combat operations, or the environment. These efforts have direct relationships with soldier survivability and lethality through improved soldier mental and physical performance. This program is managed by the U.S. Army Medical Research and Materiel Command. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).</p> <p>Core projects without R-2A Exhibits which contain less than \$1M in FY 2003 are described below: Project 837, (\$888) Soldier System Advanced Protection, supports demonstration and validation of preventive medicine materiel including devices, pharmacologicals, and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions.</p>										

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BUDGET ACTIVITY

**4 - Demonstration/validation**

PE NUMBER AND TITLE

**0603807A - Medical Systems - Adv Dev****B. Program Change Summary**

	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2002 PB)	15367	15506	16221
Appropriated Value	15509	20006	0
Adjustments to Appropriated Value	0	0	0
a. Congressional General Reductions	0	-134	-5823
b. SBIR / STTR	-398	0	0
c. Omnibus or Other Above Threshold Adjustments	0	0	0
d. Below Threshold Reprogramming	0	0	0
e. Rescissions	-141	0	0
Adjustments to Budget Years Since FY2002 PB	0	0	0
Current Budget Submit (FY 2003 PB )	14970	19872	10398

**Significant Changes:**

FY02- Congressional Adds totaling \$4500K (as noted below) added to this PE.

FY03 adjustment of (\$5823K) transferring responsibility for management and oversight of HIV R&D efforts to the National Institutes of Health (NIH).

**FY02 Congressional Adds:**

Project MD5 (+\$1000) IMED tools Rural Mobile Comms Platform - The objective of this one year add is to develop medical informatics decision support advances for use in battlefield and first responder settings.

Project MD4 (+\$3500) Future Medical Shelter - The objective of this one year add is to develop and conduct an evaluation of Future Medical Shelter System Prototypes.

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COST (In Thousands)				FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
808	DOD DRUG & VACC AD			4484	4038	5250	5285	5286	4317	4415	Continuing	Continuing
<p><b><u>A. Mission Description and Budget Item Justification:</u></b>This project funds program definition and risk reduction of candidate medical countermeasures such as vaccines and drugs through safety, immunogenicity, and small-scale efficacy testing in volunteers against naturally occurring infectious diseases of mission-degrading or mission-aborting potential, thereby improving deployability and survivability of forces. Work performed in laboratories and among troop populations is directed to prevent, diagnose, and treat viral, bacterial, and parasitic disease to prevent casualties, sustain operational performance, and minimize deaths and disability of armed forces during military operations. Preclinical trials, as well as phase 1, 2, and 3 trials, are performed as required for drug, vaccine, and device licensure by the U.S. Food and Drug Administration (FDA), and registration by the Environmental Protection Agency (EPA). Major advanced development contractors include Southern Research Institute, Birmingham AL; South Florida Research Institute, Miami, FL; and Kenya Medical Research Institute, Nairobi, Kenya. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).</p>												
<p><b><u>FY 2001 Accomplishments:</u></b></p> <ul style="list-style-type: none"><li>981 Completed and/or continued studies, and conducted reviews of malarial/antimalarial vaccines, drugs, and diagnostics:<ul style="list-style-type: none"><li>- Completed phase 1 safety study for RTS,S malaria vaccine.</li><li>- Continued developmental testing of prototype kit for the rapid detection of Plasmodium-infected mosquitoes.</li><li>- Conducted developmental testing of prototype malaria rapid diagnostic device.</li></ul></li><li>661 Conducted trials and reviews of diarrheals:<ul style="list-style-type: none"><li>- Completed a phase 1 safety trial for Shigella flexneri vaccine in Bangladesh; chosen for the high endemic occurrence of this disease and suitable medical infrastructure.</li></ul></li><li>1167 Conducted evaluations and trials of grouped infectious disease vaccines and drugs (Hepatitis E, and Leishmania):<ul style="list-style-type: none"><li>- Conducted a phase 2 multi-year field trial in Nepal, an area of high endemicity, to evaluate the effectiveness of the Hepatitis E vaccine.</li><li>- Conducted animal potency evaluation of Leishmania skin test components for the diagnosis of Leishmania infections.</li><li>- Manufactured paromomycin/gentamicin topical antileishmanial cream for future evaluation in clinical trials.</li></ul></li></ul>												

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<p><b><u>FY 2001 Accomplishments: (Continued)</u></b></p> <ul style="list-style-type: none"> <li>• 1082 Conducted or completed evaluations of Flavivirus vaccines: <ul style="list-style-type: none"> <li>- Completed development of human challenge model for the clinical evaluation of the efficacy of dengue tetravalent vaccines.</li> <li>- Completed sequencing and cloning of dengue types 2, 3, and 4 for use in evaluation of infectious clone vaccines.</li> <li>- Conducted preclinical effectiveness evaluation of a prototype infectious clone dengue vaccine.</li> </ul> </li> <li>• 593 Conducted or continued appropriate testing and review of insect vector control products: <ul style="list-style-type: none"> <li>- Continued developmental testing of a prototype lethal ovitrap for dengue vectors.</li> <li>- Conducted developmental testing of camouflage face paint with insect repellent and reduced infrared signature.</li> </ul> </li> </ul> <p>Total 4484</p> <p><b><u>FY 2002 Planned Program</u></b></p> <ul style="list-style-type: none"> <li>• 855 Conduct trials, testing, and reviews of malarial/antimalarial vaccines, drugs, and diagnostics: <ul style="list-style-type: none"> <li>- Conduct phase 1 clinical trial of new dose regimen of RTS,S malaria vaccine with a new adjuvant.</li> <li>- Continue developmental testing of prototype kit for the rapid detection of Plasmodium-infected mosquitoes.</li> <li>- Conduct Milestone (MS) C In Process Review (IPR) for the malaria rapid diagnostic device program.</li> </ul> </li> <li>• 184 Conduct and/or complete clinical trials, evaluations, and reviews of diarrheal vaccines: <ul style="list-style-type: none"> <li>- Conduct expanded phase 2 safety and efficacy field trial for Shigella flexneri vaccine in Bangladesh and conduct MS B IPR.</li> <li>- Conduct a program initiation IPR for the Shigella dysenteriae vaccine program.</li> </ul> </li> <li>• 1556 Conduct trials and reviews for grouped infectious disease vaccines and drugs (Hepatitis E, Leishmania, Group B Meningitis, and Japanese Encephalitis): <ul style="list-style-type: none"> <li>- Continue a multi-year phase 2 field trial in Nepal to evaluate the effectiveness of the Hepatitis E vaccine.</li> <li>- Produce phase 1 and phase 2 Good Manufacturing Practices (GMP) test kits, and conduct a phase 1 safety trial for the Leishmania skin test program.</li> <li>- Conduct phase 2 clinical trial of paromomycin/gentamicin topical antileishmanial cream to treat Old World leishmaniasis.</li> <li>- Conduct a program initiation IPR for the Group B Meningitis vaccine program.</li> </ul> </li> </ul>		

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<p><b><u>FY 2002 Planned Program (Continued)</u></b></p> <ul style="list-style-type: none"> <li>1377 Conduct phase 1 safety evaluation of a prototype infectious clone dengue Flavivirus vaccine.</li> <li>66 Proceed with developmental testing and evaluation of insect vector control products: <ul style="list-style-type: none"> <li>- Complete developmental testing of camouflage face paint with insect repellent and reduced infrared signature and conduct MS B/C IPR.</li> </ul> </li> </ul> <p>Total 4038</p> <p><b><u>FY 2003 Planned Program</u></b></p> <ul style="list-style-type: none"> <li>294 Conduct reviews, evaluations and trials of malarial/antimalarial vaccines, drugs, and diagnostics: <ul style="list-style-type: none"> <li>- Conduct a MS B IPR for the RTS,S malaria vaccine.</li> <li>- Conduct a MS C IPR for the rapid detection of Plasmodium-infected mosquitoes program.</li> <li>- Conduct a program initiation IPR for artelinic acid for the treatment of severe and complicated malaria.</li> </ul> </li> <li>840 Conduct and complete safety evaluations of diarrheal vaccines: <ul style="list-style-type: none"> <li>- Conduct a MS B IPR for the Shigella sonnei vaccine.</li> <li>- Complete phase 2 clinical efficacy evaluation of Shigella sonnei vaccine for the prevention of traveler's diarrhea.</li> <li>- Conduct a phase 1 clinical safety evaluation of the Shigella dysenteriae vaccine.</li> </ul> </li> <li>2469 Conduct evaluation and review of grouped infectious disease vaccines and drugs (Japanese Encephalitis, Hepatitis E, Group B Meningitis, Leishmania and Hantavirus): <ul style="list-style-type: none"> <li>- Complete a multi-year phase 2 field trial in Nepal to evaluate the effectiveness of Hepatitis E vaccine.</li> <li>- Conduct a MS B IPR for the Leishmania skin test program.</li> <li>- Complete the phase 2 clinical trial of paromomycin/gentamicin topical antileishmanial cream to treat Old World leishmaniasis.</li> <li>- Conduct phase 1 clinical safety evaluation of the Group B Meningitis vaccine.</li> <li>- Conduct a program initiation IPR and transition the hantavirus vaccine program to the next phase of development.</li> </ul> </li> <li>1518 Conduct phase 2 challenge evaluation of an infectious clone dengue tetravalent Flavivirus vaccine.</li> <li>129 Complete test and evaluation, and conduct review for insect vector control products: <ul style="list-style-type: none"> <li>- Complete developmental testing of a prototype lethal ovitrap for dengue vectors.</li> </ul> </li> </ul>		

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4 - Demonstration/validation

PE NUMBER AND TITLE

0603807A - Medical Systems - Adv Dev

PROJECT

808

## FY 2003 Planned Program (Continued)

- Conduct MS B/C IPR for the lethal ovitrap for dengue vectors program.
- Preplanned product improvement to develop new dispensers for camouflage face paint with insect repellent and reduced infrared signature.

Total 5250

**B. Other Program Funding Summary:** Not applicable for this item.

**C. Acquisition Strategy:** Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure and EPA registration.

## D. Schedule Profile

	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Leishmania Skin Test (MS B)			1Q				
Shigella flexneri (MS B)		2Q					
Paromomycin/Gentamicin (MS B)					2Q		
Hepatitis E vaccine (MS B)				1Q			
RTS,S malaria vaccine (MS B)			1Q				
Malaria Rapid Diagnostic Device (MS B)		2Q					
Camouflage face paint (MS B/C)		3Q					
Dengue tetravalent vaccine (MS B)						1Q	
Lethal ovitrap for dengue-infected mosquitoes (MS B/C)			2Q				
Detection of Plasmodium-infected mosquitoes (MS B/C)			1Q				
Shigella sonnei vaccine (MS B)			1Q				
Group B meningitis vaccine (MS B)		3Q			3Q		
Shigella dysenteriae vaccine (MS B)		3Q				3Q	

ARMY RDT&E COST ANALYSIS(R-3)									February 2002			
BUDGET ACTIVITY 4 - Demonstration/validation					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 808		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			1234	1092		987		1231		Continue	4544	0
Subtotal:			1234	1092		987		1231		Continue	4544	0
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			236	118		106		132		Continue	592	0
Subtotal:			236	118		106		132		Continue	592	0

ARMY RDT&E COST ANALYSIS(R-3)									February 2002			
BUDGET ACTIVITY 4 - Demonstration/validation					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 808		
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			4393	2820		2570		3206		Continue	12989	0
Subtotal:			4393	2820		2570		3206		Continue	12989	0
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			995	454		410		511		Continue	2370	0
Subtotal:			995	454		410		511		Continue	2370	0
Project Total Cost:			6858	4484		4073		5080		Continue	20495	0



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BUDGET ACTIVITY 4 - Demonstration/validation				PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 811			
COST (In Thousands)				FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
811	MIL HIV VAC&DRUG DEV			5529	6286	0	0	0	0	0	0	17752
<p><b><u>A. Mission Description and Budget Item Justification:</u></b>This project funds Congressionally mandated, militarily relevant human immunodeficiency virus (HIV) research for demonstration and validation of candidate vaccines and drugs through safety, immunogenicity, and small-scale efficacy testing and behavioral intervention in volunteers. Preclinical trials, as well as phase 1, 2, and 3 trials, are performed as required for drug, vaccine, and device licensure by the U.S. Food and Drug Administration (FDA). Development efforts are directed to answer militarily unique needs affecting manning, mobilization, and deployment. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).</p>												
<p><b><u>FY 2001 Accomplishments:</u></b></p> <ul style="list-style-type: none"><li>50 Completed phase 1 clinical trials to select optimal dose levels of boost component of HIV vaccines (clade E).</li><li>2422 Continued multi-year phase 2 clinical trials to down-select among three boost HIV vaccine component candidates (clade E).</li><li>3057 Conducted field site development. Conducted studies to identify potential subject populations for involvement in phase 3 pivotal clinical trial of prime-boost HIV vaccine (clade E).</li></ul> <p>Total 5529</p>												
<p><b><u>FY 2002 Planned Program</u></b></p> <ul style="list-style-type: none"><li>609 Complete multi-year phase 2 clinical trials to down-select among three HIV vaccine boost candidates (clade E).</li><li>2519 Conduct field site development to determine best location for vaccine trials in area with high HIV rate. Conduct studies to identify potential subject populations for involvement in phase 3 pivotal clinical trial of a prime-boost HIV vaccine (clade E).</li><li>50 Select boost component of HIV vaccine candidate. Conduct MS B IPR on prime-boost HIV vaccine (clade E).</li><li>3108 Plan and begin multi-year phase 3 clinical trial to determine effectiveness of prime-boost HIV vaccine (clade E).</li></ul> <p>Total 6286</p>												

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 <b><u>FY 2003 Planned Program</u></b> Program transferred to National Institutes of Health.  <b><u>B. Other Program Funding Summary:</u></b> Not applicable for this item.  <b><u>C. Acquisition Strategy:</u></b> Test and evaluate commercially developed vaccine candidates in government-managed trials.  <table border="1"><tr><td><b><u>D. Schedule Profile</u></b></td><td><b><u>FY 2001</u></b></td><td><b><u>FY 2002</u></b></td><td><b><u>FY 2003</u></b></td><td><b><u>FY 2004</u></b></td><td><b><u>FY 2005</u></b></td><td><b><u>FY 2006</u></b></td><td><b><u>FY 2007</u></b></td></tr><tr><td>HIV Vaccine (MS B)</td><td></td><td>2Q</td><td></td><td></td><td></td><td></td><td></td></tr></table>								<b><u>D. Schedule Profile</u></b>	<b><u>FY 2001</u></b>	<b><u>FY 2002</u></b>	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>	<b><u>FY 2006</u></b>	<b><u>FY 2007</u></b>	HIV Vaccine (MS B)		2Q					
<b><u>D. Schedule Profile</u></b>	<b><u>FY 2001</u></b>	<b><u>FY 2002</u></b>	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>	<b><u>FY 2006</u></b>	<b><u>FY 2007</u></b>																
HIV Vaccine (MS B)		2Q																					

ARMY RDT&E COST ANALYSIS(R-3)									February 2002			
BUDGET ACTIVITY 4 - Demonstration/validation					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 811		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	3698	595		846		0		Continue	5139	0
Subtotal:			3698	595		846		0		Continue	5139	0
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			157	339		372		0		0	868	0
Subtotal:			157	339		372		0		0	868	0
Remarks: Not Applicable												

ARMY RDT&E COST ANALYSIS(R-3)									February 2002			
BUDGET ACTIVITY 4 - Demonstration/validation					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 811		
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Test and Evaluation	Government Laboratory	Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD	2037	4497		4961		0		0	11495	0
Subtotal:			2037	4497		4961		0		0	11495	0
Remarks: Not Applicable												
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually.			45	98		107		0		0	250	0
Subtotal:			45	98		107		0		0	250	0
Remarks: Not Applicable												
Project Total Cost:			5937	5529		6286		0		Continue	17752	0

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BUDGET ACTIVITY 4 - Demonstration/validation				PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 836			
COST (In Thousands)				FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
836	COMBAT MEDICAL MATL AD			4134	4164	4260	4210	4258	4198	4394	Continuing	Continuing
<p><b><u>A. Mission Description and Budget Item Justification:</u></b>The project supports advanced development of new and improved systems essential for battlefield casualty care, patient transport and evacuation, and return to duty in support of special contingency and conventional force operations. These systems decrease mortality rates and enhance force sustainment by providing more responsive, versatile, and deployable forward health care. Advanced development contractors/universities includes Mainstream Engineering Corp, Energy Systems Technology, Inc. Mission Medical; IGR Enterprises, Inc; Bell Products and American Red Cross. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).</p>												
<p><b><u>FY 2001 Accomplishments:</u></b></p> <ul style="list-style-type: none"><li>1925 Developed solicitation package, published a request for proposal and secured commercial partner for Hemostatic Dressing (HD) development.</li><li>110 Developed and tested medical evacuation systems.<ul style="list-style-type: none"><li>- Developed a lightweight platform, Special Medical Emergency Evacuation Device (SMEED), to carry military-approved commercial off-the-shelf medical devices for patient treatment during evacuation.</li></ul></li><li>1997 Conducted transitions and product evaluations of field medical treatment and treatment aid devices.<ul style="list-style-type: none"><li>- Integrated prototype modules into a portable Ceramic Oxygen Generator System (COGS) to demonstrate acceptable medical oxygen generation capability for individual patients.</li><li>- Began evaluation of the use of oxygen concentrators and oxygen rebreathing devices as a step towards development of the Ventilatory Assist Device (VAD) for operating room use.</li><li>- Designed and fabricated lightweight motors and compressors for the Pressure Swing Adsorption Oxygen Generator (PSAOG) for multiple patients in a ward-like setting.</li><li>- Completed a MS A and a Program Initiation for the Dental Field Treatment and Operating System (DEFTOS), and began reliability/survivability tests.</li><li>- Completed a MS A and a Program Initiation for the One-Handed Tourniquet.</li></ul></li></ul>												

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<p><b><u>FY 2001 Accomplishments: (Continued)</u></b></p> <ul style="list-style-type: none"> <li>- Completed a market investigation for the Dental Filmless Imaging System (DFIS).</li> <li>• 102 Prepared and conducted tests and investigations for medical monitoring and imaging systems.</li> <li>- Integrated the Warrior Medic "911" button software into the Land Warrior System.</li> </ul> <p>Total 4134</p> <p><b><u>FY 2002 Planned Program</u></b></p> <ul style="list-style-type: none"> <li>• 1947 Conduct animal trials required by FDA and prepare Investigational New Drug application for FDA for the Hemostatic Dressing.</li> <li>• 302 Demonstrate and evaluate medical evacuation systems.</li> <li>- Conduct an air-worthiness evaluation of the SMEED.</li> <li>• 1748 Conduct testing and Milestone In Process Reviews (IPRs) for field medical treatment and treatment aid devices.</li> <li>- Perform COGS technical testing, and conduct a MS A and Program Initiation.</li> <li>- Complete evaluation of the use of oxygen concentrators and oxygen rebreathing devices for operating room use as a step towards development of the VAD.</li> <li>- Integrate compressor design and the molecular sieve bed into a PSAOG. Conduct a Program Initiation IPR.</li> <li>- Complete the reliability/survivability tests for the DEFTOS and conduct a MS B/C.</li> <li>- Down select to single One-Handed Tourniquet design.</li> <li>• 167 Conduct tests and investigations for medical monitoring and imaging systems.</li> <li>- Conduct an initial operational test and evaluation for the Warrior Medic System and prepare for a MS B/C.</li> <li>- Conduct MS C to recommend Dental Filmless Imaging System for procurement.</li> </ul> <p>Total 4164</p>		

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BUDGET ACTIVITY

4 - Demonstration/validation

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0603807A - Medical Systems - Adv Dev

PROJECT

836

## FY 2003 Planned Program

- 1940 Continue testing of the Hemostatic Dressing and prepare for a MS B.
- 493 Continue development of medical evacuation systems.  
- Complete testing of the SMEED system.
- 1729 Perform development, testing and IPRs for field medical treatment/treatment aid devices.  
- Conduct a pre-production development for the COGS.  
- Conduct the development of the VAD for anesthesia and ventilation at forward surgical team sites.  
- Perform a detail testing of the PSAOG.
- 98 Conduct testing/IPRs on medical monitoring and imaging systems.  
- Complete the Warrior Medic System initial operational test and evaluation. Prepare for a MS B/C IPR.

Total 4260

**B. Other Program Funding Summary:** Not applicable for this item.

**C. Acquisition Strategy:** Evaluate commercially developed materiel in government-managed tests for hardening or other modification.

## D. Schedule Profile

	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Ceramic Oxygen Generator System (MS A and Program Initiation IPR)		1Q					
Pressure Swing Adsorption Oxygen Generator (Program Initiation IPR)		1Q					
One-Handed Tourniquet (MS A with program initiation)	4Q						
Dental Filmless Imaging System (MS C)		2Q					
Warrior Medic systems - MS B/C			4Q				

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)						February 2002			
BUDGET ACTIVITY 4 - Demonstration/validation			PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev				PROJECT 836		
<u>D. Schedule Profile (continued)</u>			<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>
Hemostatic Dressing (MS B)					1Q				
Dental Field Treatment and Operating System (MS A with program initiation); (MS B/C)			3Q	4Q					



ARMY RDT&E COST ANALYSIS(R-3)									February 2002			
BUDGET ACTIVITY 4 - Demonstration/validation					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 836		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Hemostatic Dressing		Red Cross, Charlotte, N.C.	0	1675	4Q	1947		1940		Continue	5562	0
b . No other contract exceeds \$1M			11824	0		0		0		0	11824	0
Subtotal:			11824	1675		1947		1940		Continue	17386	0
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:			0	0		0		0		0	0	0
Remarks: No product/contract costs greater than \$1M individually.												

ARMY RDT&E COST ANALYSIS(R-3)									February 2002			
BUDGET ACTIVITY 4 - Demonstration/validation					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 836		
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
			0	0		0		0		0	0	0
Subtotal:												
Remarks: No product/contract costs greater than \$1M individually.												
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$M individually.			0	2459		2217		2320		0	6996	0
Subtotal:			0	2459		2217		2320		0	6996	0
Project Total Cost:			11824	4134		4164		4260		Continue	24382	0